

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**40249**

**ADMINISTRATIVE DOCUMENTS**

**RECORD OF TELEPHONE CONVERSATION**

**DATE:** December 14, 1998

**PRODUCT NAME:** Orphenadrine Citrate Extended-release Tablets, 100 mg

**ANDA NUMBER:** 40-249

**FIRM NAME:** Kiel Laboratories, Inc.

**NAME AND TITLE OF PERSONS WITH  
WHOM CONVERSATION WAS HELD:**

Kiel Laboratories: Tanyja Scott

FDA: Michael Smela, Team Leader  
Shirley Brown, Chemist

**PARTICIPANT(S) TELEPHONE:** Kiel Laboratories (770) 534-0079

**MINUTES OF CONVERSATION:**

One issue was discussed with Kiel Laboratories.

Per the November 25, 1998 amendment, the proposed stability specification of % for the impurity is not acceptable. Full term stability data for impurities report non detected. The applicant proposed to revise the specification to NMT % and to submit the information in a Telephone Amendment today. The Telephone Amendment will be followed by a hard copy.

**NAMES OF OGD REPRESENTATIVES:** Shirley S. Brown  
Michael J. Smela, Jr.

**SIGNATURES OF OGD REPRESENTATIVES:**

/S/  
J

12/15/98

**DIVISION/BRANCH:** OGD, Chemistry I/HFD-625

/S/ 12/15/98